

REMARKS

Claims 68-72, and 76-114 are now pending. Claims 69-71 and 73-75 are canceled without prejudice or disclaimer. New claims 96-114 find support in original claims 1-26 and 36. No new matter is added. The present claims have been limited for reasons not related to patentability to the fungi of the genus *Mortierella* as defined in now canceled claim 71.

The following remarks are in response to the rejections made in the final office action dated March 29, 2005.

The rejection of claims 68-95 under 35 U.S.C. § 112, second paragraph is traversed. Claim 68 has been amended to delete the term “for weeks” to which the Office objected. Thus, removal of this rejection is respectfully requested.

The rejection of claims 68-95 under 35 U.S.C. § 103(a) as being unpatentable over Barclay taken with Carduck, Akimoto, Casey, and Remington is traversed. Carduck no longer appears relevant because this reference is directed to the production of live yeast granules. Also, Casey, which was cited for its disclosure of *Pichia*, is no longer relevant to the claims, as only fungi of the genus *Mortierella* is defined in claim 68.

According to MPEP § 2142, three basic criteria must be met to establish *prima facie* obviousness: (1) the prior art must teach or suggest all of the claimed limitations; (2) there must be motivation to combine the references; and (3) there must be a reasonable expectation that the combination will be successful. *Prima facie* obviousness has not been established with respect to any of these criteria. With respect to the claim limitations, the Examiner has not fulfilled her burden of establishing *prima facie* obviousness because, at a minimum, a) the Examiner has not established that the references teach or suggest the microorganism is dead as defined in claim 68, b) the Examiner has not established that the references teach or suggest the size of the granules as defined in claims 68 and 87-90, c) has the Examiner not established that the references teach or suggest granules having a dry matter content as defined in claims 83-85, and d) the Examiner has not established that the references teach or suggest the porosity of the granules as defined in claim 68

and 91-94. The Office alleges that a lesser burden of proof is required to establish *prima facie* obviousness for product-by-process claims, but such does not excuse the Office from providing references that disclose or suggest each element of the claimed invention. As discussed above, there are at least four elements in the prior response that are not found in the references cited by the Examiner, all of which make no reference to a process.

Further, Barclay specifically teaches away from using *Mortierella* organisms in its process. Barclay stated that *Mortierella* organisms were not good candidates for commercial production of ω -3 highly unsaturated fatty acids because *Mortierella* fungi have low amounts of such compounds, as discussed in column 3, lines 43-60 therein. Rather, the object of the Barclay invention is to produce commercially practical levels of ω -3 highly unsaturated fatty acids using different organisms, as discussed in column 4, lines 47-51 therein. Specifically, the invention according to Barclay is

directed toward a food product with a high concentration of omega-3 highly unsaturated fatty acids (HUFAs) which includes *microorganisms characterized by having a high concentration of fatty acids of which a high percentage are omega-3 highly unsaturated fatty acids.* (Emphasis added.)

Even if, for the sake of argument, Akimoto or another reference provided motivation to use *Mortierella* organisms in their process, there would be no expectation that such a combination would be successful, as these organisms have been cited as being poor candidates for the process of Barclay's invention. The Office has not provided a rationale to support a proper motivation that a skilled artisan would substitute fungi of the genus *Mortierella* for Barclay's chloroplast-containing organisms. As discussed above, the nature of the organism is important in Barclay rather than the nature of the formulation as claimed.

In addition, applicants submit that there is no motivation to combine Barclay or Akimoto. Neither Barclay nor Akimoto teach granulation or extrusion of *Mortierella* organisms as claimed. Akimoto discloses a method of producing a particular fatty acid (bishomo- γ -linolenic acid) by suppressing the production of arachidonic acid in organisms such as *Mortierella*, among

others. Akimoto's process is very specific in that the culture medium is important to the production of the bishomo- γ -linolenic acid, namely a culture medium must contain sesame oil or peanut oil, among other additives. There is no connection between Barclay and Akimoto because two different processes are disclosed. Akimoto also does not overcome Barclay's teaching that *Mortierella* is unsuitable for commercial production of ω -3 highly unsaturated fatty acids as described above. In addition, the extraction methods in Akimoto (column 6) and Barclay (column 13) are different and do not suggest granulation or extrusion. The Office has provided no motivation to combine these references, nor has the Office established why the combination of these references would have a reasonable expectation of success.

The Office appears to conclude in the final action that the composition must read on Barclay because the dry ground grain such as corn is said not to affect the material characteristics of the claimed invention. However, the purpose of the composition is to provide a storage stable form which is appropriate for extracting nutrients *in vitro*. The extra inert material would materially affect the characteristics of the composition as it was subjected to the extraction procedure. Thus, the additional components indeed would materially change the characteristics of the applicants' invention.

In addition, the Office alleges that the extruded microbial product can reasonably be "presumed" to be stable for weeks due to Carduck's disclosure. However, Carduck is no longer relevant to the present claims, as it does not disclose dead *Mortierella* organisms as claimed. Nonetheless, it appears that the Office is suggesting that stability is inherent in Barclay's material. However, inherency is not relevant to a finding of obviousness in this case because the granules as claimed have this property, but no reference discloses such granules *per se*.

Although Carduck is no longer relevant, applicants take issue with the Office's suggestion that applicants have not demonstrated that the properties of Carduck's granules are altered due to Carduck's living organisms. It is respectfully submitted that the burden has been improperly shifted to applicants. Rather, if it was relevant, the Office would be required to establish that there is no difference whether the yeast is dead or alive. In addition, the Office appears to

ignore the difference in the nature of the porosity generated by drying as claimed and that deliberately conferred on Carduck's composition. The compositions are simply different, and the Office has not shown otherwise.

For these reasons, *prima facie* obviousness has not been established, and withdrawal of this rejection is respectfully requested.


Applicants request a telephonic interview with the Examiner and her supervisor if the Examiner is not convinced that the present claims contain allowable subject matter.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 251502006900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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